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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,855	02/14/2001	Dann LeRoy Parker JR.	20526Y	9302

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EXAMINER
COVINGTON, RAYMOND K

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 11/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/994,091	REINHARDT ET AL.	
	Examiner	Art Unit	
	Raymond Covington	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/22/02,5/28/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 19-21* is/are rejected.

7)☐ Claim(s) *10-18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn et al US 4,704,472 taken with Pietruszkiewicz et al US 4,835,313.

Conn et al US '472 teach fluorene derivatives of the type recited in the claims. For example, where applicants' formula in claim 1, X=O, R^6 = RO, R^3 = chloro and R^{10} = C_3 alkyl. See column 1 lines 35+ and claim 1. Patentees differ from in that they do not recite all possible combinations falling within the scope of the recited claims. However, Pietruszkiewicz et al US '313 teach that other analogous compounds would have been obvious to one of ordinary skill in the art due to the close structural relationship between the compounds. This is particularly true in light of the similar utilities between the references, which would give one a reason to modify Conn et al US '472. It is further noted that the claimed compounds would have been obvious notwithstanding any intended use.

The specification does not give any guidance as to the full range of conditions, which could be treated or prevented using the instant claimed process. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. The nature of the invention,

2. The state of the prior art,

3. The predictability or lack thereof in the art,

4. The amount of direction or guidance present,

5. The presence or absence of working examples,

6. The breadth of the claims,

7. The quantity of experimentation needed, and

8. The level of the skill in the art.

In the instant case, Applicants are claiming a method of preventing, hot flashes, anxiety or depression. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant specification does not give any guidance as to how the instant claimed process effects the full range modalities and mechanisms necessary to completely prevent the conditions claimed. I.e. more than one thing causes, for example, depression. In order to practice the claimed invention, one skilled in the art would have to speculate which conditions could be prevented using the claimed compounds found in the instant claims. The number of possible conditions embraced by the claims would impose undue experimentation on the skilled art worker. Therefore, the broad terminology treatment or prevention is not enabled because the metes and bounds of conditions that could be treated or prevented cannot be ascertained.

Claims 19-21are rejected under 35 U.S.C. 112(first paragraph) on the grounds of an insufficient disclosure of utility. Specifically, the terminology "treating or preventing hot

flashes, anxiety or depression" not believable in view of the contemporary knowledge of the art for the reasons set forth in the next above paragraph.

Claims 10-18 are objected to as dependent from a rejected base claim.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

The specification does not give any guidance as to how each of the

derivatives were prepared. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, Applicants are claiming derivatives. Applicants have not disclosed any working examples, which would demonstrate, or guide, one skilled in the art as to how these derivatives were prepared or obtained, the process of making these derivatives or how they were obtained is not readily apparent from the specification. The specification must teach how to

make the invention. *In re Gardner*, 166 U.S.P.Q. 138 (1970). In order to practice the claimed invention, one skilled in the art would have to speculate how the derivatives were obtained or prepared. Therefore, the instant invention is not enabled. The rejection is applied as in the previous office action. Applicants comments have been noted and considered but are not deemed persuasive of Patentability. The exemplification of two heteroaryl groups, namely thiophenyl and furanyl, is no way supportive of the vast number of known heterocyclic groups encompassed by the claims as presently recited. For example, the disclosed heteroaryl examples would not suggest how to make or use derivatives containing quinoline, benzopyrimidine, morpholine, oxathiazines and other heteroaryl groups.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (703) 308-4704. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, A. Rotman can be reached on (703) 308-0204. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7922 for regular communications and (703_ 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Raymond Covington
Examiner
Art Unit 1625

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Covington/dl
November 5, 2002

Alan L Rotman

ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600